Docket No.: 595992000600
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Daniel V. PALANKER et al.

Application No.:	10/779,529	Confirmation No.:	5591
Filed:	February 13, 2004	Art Unit:	3739
For:	ELECTROSURGICAL SYSTEM WITH UNIFORMLY ENHANCED ELECTRIC FIELD AND MINIMAL COLLATERAL DAMAGE	Examiner:	P. Vrettakos

DECLARATION UNDER RULE 132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

1. I have been retained and paid by Peak Surgical Inc. to prepare this Declaration. I have reviewed the specification of the above cited Palanker et al. US Application No. 10/779,529, the pending claims, the Office Action dated March 9, 2007, Malis et al. US 4,590,934 (hereinafter "Malis"), and Heim et al. US 6,533,781 (hereinafter "Heim").

2. I am very familiar with the field of electrosurgery, which is the technical discipline of applying radio frequency electrical current to biological tissue for the purpose of tissue cutting and coagulation. As shown in my attached resume, I have been responsible for the design and development of medical devices and products since 1983. I have been active in the design and specification of electrosurgical devices since 1988.

3. I conclude that one of ordinary skill in the art of electrosurgery would have a minimum of a four-year degree in electrical or biomedical engineering, and two or more years

experience in product development and design of medical devices and further at least two years experience in the design and development of electrosurgical generators.

4. I understand that in the above cited Palanker et al. patent application, Claims 1-14, 18-27 and 35-40 are currently under examination. I understand that the Patent Examiner believes that the feature in Claim 1 pertaining to the configuration of the cutting blade is met or made obvious by Heim. However, I believe that Heim does not meet the present claims and especially does not meet the feature in Claim 1 that "said cutting portion has an in-plane radius of curvature that is at least 10 times larger then said edge radius of curvature along the entire length of said cutting portion." Further, I believe that Heim does not meet this portion of Claim 1 either explicitly or inherently. Further, I believe for the reasons set forth below that Heim would not make obvious to one of ordinary skill in the art this feature of Claim 1. That is, I believe it is not the case that one of ordinary skill in the art by routine experimentation would arrive at this feature of Claim 1 based on the Heim disclosure.

5. Heim discloses various configurations of his blade in his Figures 1-5. His stated technical goal in terms of his blade is to reduce smoke generation and reduce eschar (charring), see column 2, lines 1-10. To do this, I understand that Heim has a blade which effectively acts as a heat sink to remove unwanted heat generating during the electrosurgery from the surgical site (the cut or coagulated area of tissue). Further, Heim achieves this by providing his blade with a very thin edge thickness indicated by him as being about 0.001 inch thick or less, see Heim column 5, lines 1 and 2.

6. In contrast, the blade configuration recited in present Claim 1 is significantly different. The claimed blade configuration effectively results in a somewhat rounded blade edge rather than a very sharp edge disclosed by Heim. It is my understanding that the blade in accordance with Claim 1 provides very precise sub-cellular tissue cutting via a particular plasma vaporization regime. This blade results in an evenly distributed electrical field around the blade for generating plasma, eliminating hotspots and resulting in a uniform surgical effect on the target tissue. This is a significant improvement over Heim. Especially I believe the improvement is significant because this allows more precise cutting with less burning of the tissue using a relatively

low energy input due to the particular plasma regime, resulting from both the blade configuration and also the particular nature of the energizing electric current applied to the blade.

7. Therefore I believe that the blade configuration recited in Claim 1 provides much superior results to those of Heim, and one of ordinary skill upon review of Heim would not have any motivation or reason to modify the blade of Heim in order to arrive at the Claim 1 blade configuration.

8. As regards Malis, I understand this reference was cited by the Examiner as meeting the feature in Claims 1 and 35 and directed to the pulsed energy and the source of pulsed energy applied to the blade. First, I believe that Malis does not meet, explicitly or inherently, the feature recited in Claim 1 that "said source of pulse electrical energy is configured to apply a plurality of burst of pulses...wherein the duration of the burst of pulses is 1 ms or less;". Malis FIG. 18(f) shows the pulse duration ("ON") being 6 ms. The accompanying text of Malis at column 9, lines 13-44 further describes the 6 ms long burst. See also Malis column 10, lines 39-43, describing this 6 ms burst used for the cut waveform. So, Malis does not meet this feature of Claim 1. Further, I believe that Malis does not make this feature of Claim 1 obvious to one of ordinary skill in the art, and one of ordinary skill in the art upon review of Malis would not arrive at the burst configuration of Claim 1 for the reasons set forth below. This conclusion as regards Claim 1 also pertains to Claim 35.

9. Malis appears to disclose a well known apparatus sold by Johnson & Johnson referred to as a Codman apparatus and primarily used for electrosurgery coagulation. The chief objective of Malis (see column 1, lines 13-18 and column 3, lines 9-12) is in connection with coagulation (not cutting), and is to control the initial burst voltage to eliminate the undesirable voltage spike which occurs in the prior art coagulation apparatus. Further, it appears to me that the Malis apparatus is suitable for cutting conductive tissue, such as neurological tissue (nerves). Neurological tissue is electrically conductive by nature and thereby is relatively easy to cut by electrosurgery compared to other tissues, such as skin, muscle or organs. Therefore I believe that the Malis pulse configuration, in conjunction with a conventional blade, would likely do a good job

of cutting neurological tissue and also of coagulating, but is not optimal for cutting other types of tissue.

10. Moreover, Malis discloses the length of his pulse bursts as being 6 ms for cutting. I believe that the Malis apparatus would likely not be operative for cutting any type of tissue if Malis were to use significantly shorter length bursts, since this would not apply to the blade enough electrical energy to generate a plasma suitable for cutting. In other words, shorter bursts would not deliver enough electrical power for cutting. Especially, I believe that the difference between the 6 ms length of burst of Malis and the 1 ms burst recited in Claim 1 is technically significant and more than a routine engineering difference. This is because I believe that one of ordinary skill in the art would not see to modify Malis to have shorter bursts, since it would be understood by him that a shorter burst would not deliver enough electrical power for cutting tissue, especially in combination with any conventional type of electrosurgery blade.

11. In contrast, as I stated above, Claim 1 (and Claim 35) recite a 1 ms length burst. This is advantageous in that the short burst results in lower delivery of electrical energy and hence less localized tissue heating with less tissue damage. I understand that in combination with the particular blade of Claim 1, for instance, this provides sufficient energy for cutting tissue.

12. Thus I believe that the length of burst recited in Claim 1 (and Claim 35) is a significant technical distinction over the longer pulse burst of Malis, and also provides superior results.

13. I declare that all statements made here and of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Title 18, Section 1001 of the United States Code, and that such willful false statements may jeopardize the validity of the above patent application or any patent issued thereon.

Signed:

Harold J. Walbrink

Date: July 7, 2007

Harold J. Walbrink

Senior Medical Device Industry Executive

58 Coronado Pointe
Laguna Niguel, California 92677

Tel: (949) 249-0410
Cell: (949) 697-9462
Email: xinetix-inc@cox.net

Summary

Career achievements include: six business startups, three business turnarounds, seven project turnarounds, over fifty new products developed and five medical device patents.

Accomplished senior level high-tech executive with 30 years product development and general management experience within healthcare (22 years), commercial, and aerospace industries. Proven ability to successfully deliver significant revenue and asset growth through identification, development, and implementation of innovative business and technology solutions. Broad experience base ranging from startup to later-stage private and public companies in domestic and international markets.

Accomplishments and Qualifications

- Proven ability to deliver innovative and effective technology solutions, products, and business growth in response to client, business and marketplace needs.
- Achieved industry recognition for successful product development and implementation for start-up, high growth, and later-stage companies; twenty two years devoted to medical device development.
- Developed products for a major ophthalmic manufacturer resulting in excess of $79 million annual sales growth over a six-year period.
- Nine US patents issued or in application.
- Negotiated international and domestic product development and OEM supply agreements.
- Direct hands on experience with project/department leadership, strategic planning, business development, corporate turnaround, down sizing, and fund raising activities.
- Extensive corporate merger, acquisition, and divestiture experience including international and domestic due diligence, negotiations, funding and implementation activities.
- Multi-disciplinary experience in general management, research and development, regulatory affairs, quality assurance, manufacturing engineering, and manufacturing for GMP/ISO compliant medical manufacturers.
- In-depth regulatory experience including: GMP and ISO regulation compliance, QSR implementation, FDA facility audits, FDA 510(k) / IDE submissions, clinical trials, and FDA 483 letter responses/resolution.
- Senior executive level experience with start-up and later stage private and public companies having annual revenue up to $56 million.
- Annual operating budget responsibility up to $21 million, employing 145 personnel, with domestic and international operations.
- Instrumental in corporate fund raising including: private placement, bridge financing, regulation S stock offering, initial and secondary public offerings and venture capital funding.
- Implemented manufacturing process improvements to realize product line inventory reductions up to 60%, and improvements in manufacturing efficiencies up to 115%, while maintaining acceptable customer service levels.
- Served as Board Chairman and/or Corporate Director for three Southern California start-up companies.

BUSINESS EXPERIENCE:

XINETIX, INC., LAGUNA NIGUEL, CA
Founder / President ***March, 1995 to Present***

Founded this highly-focused, innovative product and business development company serving startup and troubled high-technology companies on an interim management and project basis. Established a track record for on time delivery of innovative technology-based products and business solutions for domestic and international clients primarily within the healthcare industry. Assignments included strategic and business planning, Operations management, business and product development, Regulatory Affairs, and production startup. Assumed interim executive level positions as Chairman, CEO, COO, and Executive Vice President while providing general business, technical management, and product design services to over thirty client companies. Also served as an expert witness in conjunction with several product liability and patent infringement cases.

NEWPORT MEDICAL INSTRUMENTS, COSTA MESA, CA
COO / Executive Vice President ***March, 1999 to Jan. 2003***

Instrumental in successful turnaround of financially-troubled privately held Japanese critical care ventilator manufacturer with international sales of $15mil annually. Contracted as the catalyst for revitalizing this 20 year old company with outdated products, declining sales, and poor executive leadership. Increased company profitability from $2mil loss to $200K profit within two years through new product introductions, company restructuring and product / process improvements. Initiated a formal strategic planning process and established a formal corporate technology development plan and process. Successfully completed development and launch of the *e500* world-class critical care ventilator designed as the company's advanced generation product platform. Served as primary liaison to an Israeli OEM homecare and transport ventilator supplier contributing over $7mil additional annual revenue.

BIRTCHER MEDICAL SYSTEMS, IRVINE, CA
Senior Vice President, Operations and Technology ***Aug., 1994 to April, 1995***
Vice President, General Manager ***Sept., 1991 to Aug., 1992***
Vice President, Research and Development ***Jan., 1990 to Aug., 1994***

Assumed broad cross-functional responsibility for General Management, Operations, Research and Development and Regulatory Affairs as a Senior Executive Officer for this public company. Administered a $21 million operating budget for three US manufacturing facilities with 145 direct employees and a 130 man Maquilladora operation. Revenues grew from $6 to $56 million as a result of negotiating domestic and international OEM supply agreements and acquisition/consolidation of three healthcare businesses. Realized major profitability improvements through product refinement / repositioning, new product introductions, and manufacturing process improvements.

Instrumental in development of corporate technology strategy and product development activities for a diverse range of product technologies including; RF electrosurgical, video endoscopy, surgical instruments, ECG, Doppler ultrasound, and physical therapy devices. Responsible for all patent and trade mark activities including infringement litigation oversight. Inventor on five U.S. patent applications for medical devices resulting in issuance of three patents. Key contributor in corporate financing activities which including private placement, secondary, and regulation S stock offerings as well as venture capital funding. As Corporate Regulatory Officer, I was responsible for Quality Systems Regulation implementation, FDA 510(k) submissions, Engineering Change Control and Documentation Systems, and Quality Assurance programs. Led FDA GMP audits and successfully cleared a FDA 483 Warning Letter well ahead of the three month deadline.

ALCON SURGICAL, IRVINE, CA (formerly CooperVision Surgical) ***Aug., 1983 to Jan., 1990***
Director of Research and Development, Surgical Instrumentation

Responsible for identification, conceptualization, development, and technical support of ophthalmic surgical instrumentation, devices, and disposable products totaling $79 M annual sales. Provided long-range strategic direction and daily administration for five ophthalmic business segments in a department with 64 technical personnel and annual budget of $5.9 M. Recognized for the ability to develop well-targeted, innovative products and bring them to market on schedule and within budget. Chosen as team leader on a company-wide effort to improve quality of existing products. Product technologies included; surgical and diagnostic ultrasound, fluidics, microsurgical instruments, ophthalmic lasers, and micro-endoscopy. Authored the CooperVision Product Introduction Protocol and was co-inventor on five US patents.

FORMAL EDUCATION:

1975	**CALIFORNIA STATE UNIVERSITY FULLERTON, FULLERTON, CA.**
	Bachelor of Science, Engineering - Electrical emphasis
1972	**FULLERTON COLLEGE, FULLERTON, CA.**
	Associate Arts Degree, Liberal Arts

CONTINUING EDUCATION

1985	**BUSINESS KINETICS, IRVINE, CA**
	Certificate, Operations Planning and Cost Control
1982	**UNIVERSITY OF CALIFORNIA, IRVINE, IRVINE, CA.**
	Certificate, Microprocessor Systems Engineering
1981	**HEWLETT PACKARD, CONOGA PARK, CA.**
	H.P. Model 1000 & 9000 Computer Operations and Programming

ORGANIZATIONS & ACTIVITIES:

2001 – 2004	Chairman & CEO, The Source, Capistrano Beach, CA
1998 - 1999	Director, Refractec, Inc., Laguna Hills, CA
1997 – 2004	Director, Scieran Technologies, Inc., Laguna Hills, CA
1995	Speaker, Pacific Design Conference, " Partnering Effectively With Outside Consultants", Long Beach, CA
1995	Speaker, Asian / American Engineering Society Conference, "Imaging and Virtual Reality Meet Medicine", Los Angeles, CA
1993	Speaker, Medical Data International Conference on Healthcare Reform, American College of Surgeons, San Francisco, CA

PATENTS & PUBLICATIONS:

1987	Microsurgical Cassette, US Patent # 5,364,342
1991	Fluid Handling Method, System, and Apparatus US Patent # 5,041,096
1992	Laparoscopic Pressure Relief Device, Birtcher US Patent Application
1992	Laparoscopic Gas Enhanced Coagulation Handpiece, Birtcher US Patent Application
1993	Laparoscopic Surgical Handpiece, Birtcher US Patent Application
1993	Portable Device for Controlling Fluid Flow to A Surgical Site, US Patent # 5,261,883
1995	Multi-functional Probe for Minimally Invasive Surgery, US Patent # 5,449,356
1996	Irrigator/Aspirator Surgical Probe and Valve Assembly, US Patent # 5,514,089
1996	Microsurgical Cassette, US Patent # 5,499,969

Electrosurgery & Gas Plasma Expertise

Harold J Walbrink

2004 2007 **Paragon Medsystems, San Diego, CA** — **Electrosurgical Design Engineering Consultant**

Contracted to develop a specialized, high-frequency electrosurgical module designed to drive a plasma knife for precision tissue cutting. Assisted in evaluation, redesign, and testing of an electrosurgical generator for cardiac ablation to treat Wolf-White-Parkinson's disease related cardiac arrhythmia.

1993 2007 **Refractec, Inc. Irvine, CA** — **Electrosurgical Design Engineering Consultant & Board Member**

Assisted in the development of a prototype vision correction system employing electrosurgical waveforms to modify collagen within corneal tissue. Reviewed and broadened Intellectual Property in the area of electrosurgical energy applied to the cornea to achieve vision correction. Served as a Director on the Board form 1994 to 1996.

2003 2004 **Minnow Medical, Del Mar, CA** — **Electrosurgical Technology Consultant**

Electrosurgery consultant to founders. Responsible for research, clinical science, and product development of electrosurgical devices for the treatment and reduction of human arterial plaque. Worked with University of Minnesota researchers to characterize clinical effect of electrosurgical energy when applied to vessel tissue.

1999 2001 **Dermatological Lab & Supply Corporation, Council Bluffs, IA** — **Electrosurgical Design Engineering Consultant**

Contracted to design and develop a low-power, office-based electrosurgical unit for cutting and coagulating tissue. Responsible for all aspects of design engineering, safety testing and regulatory agency compliance,

2000 **Computer Motion, Golita, CA** — **Electrosurgical Design Engineering Consultant**

Assisted in the design and testing of electrosurgical electrodes for applications in robotic-assisted surgery. Setup electrosurgical testing laboratory and aided in developing world-wide regulatory agency compliant test protocols.

Mar., 2000 **Advanced Sterilization Products, Irvine, CA** — **Design of RF Plasma Generator Control Module for medical plasma sterilization systems**

Contracted to redesign hydrogen peroxide plasma generator for a series of industrial and office-based medical sterilizer product lines. Reduced generator equipment cost by 80 percent while maintaining plasma performance and stability.

April, 1999 **VIVANT Medical, Walnut Creek, CA** — **Design & Development of "Smart Bovie" Electrosurgical Pencil for biopsy.**

Specified, designed, and developed a concept prototype "Smart Bovie Knife" for guiding an electrosurgical electrode to a target surgical site in breast biopsy procedures.

1998 **Akos Biomedical, Rancho Bernardo, CA** — **Electrosurgical Design Engineering Consultant**

Consultant to the VP of R&D and the product development group on electrosurgical theory, clinical principles, and design practices. Assisted in designing instruments for the treatment of Barrett's Esophagus.

1997 1998 **Cardio Thoracic Systems, Cupertino, CA** — **Electrosurgical Design Engineering Consultant**

Provided education on basic electrosurgical principles and consulted on the design and specification of electrosurgical instruments to enable Left Mammary Artery (LMA) vessel harvesting procedures used in minimally invasive cardiac bypass surgery.

Sept, 1998 **Allegiance Healthcare,Chi cago, IL** — **Evaluation & redesign of insulating materials for electrosurgical instrumentation.**

Tested and redesigned a family of minimally invasive, electrosurgical electrodes to improve the insulating properties. Wrote test protocols in compliance with regulatory and safety agency standards, specified improved insulating materials, performed comparative current leakage and capacitive coupling testing of products.

Sept., 1998 **Bercthold Elekromedizin, GmbH, Tubingin, Germany** — **Electrosurgical Design Engineering Consultant**

Assisted in redesign of user interface appearance and function of an electrosurgical generator in order to address US customer expectations and position the Becthold electrosurgical generator for sale in the US market.

Feb., 1997 **Horizon Medical, Santa Ana, CA** — **Electrosurgical Design Engineering Consultant**

Responsible for design, manufacturing set-up, validation testing, regulatory safety agency compliance, and preparation of an FDA 510(k) submission for a family of electrosurgical return electrodes. Set up electrosurgical test laboratory.

July, 1997 **Maxxim Medical – Clearwater, FL** — **Electrosurgical Design Engineering Consultant**

Assisted in the redesign and product line upgrades of recently acquired Bovie brand electrosurgical generators and accessories.

1997 **Benderev Engineering, Laguna Hills, CA** — **Electrosurgical Design Engineering Consultant**

Contracted to provide education on the principles of electrosurgery, provide design input to develop electrosurgery based gynecological instruments and broaden intellectual property for electrosurgical instrument development projects.

1997 **Conceptus Corporation, San Carlos, CA** — **Electrosurgical Design Engineering Consultant**

Taught electrosurgical theory, clinical principles, and design practices to the product development group. Designed and tested a series of electrosurgical instruments and disposable electrodes for gynecological applications. Set up an electrosurgical test laboratory and developed test procedures.

Feb. 1995 **Imagyn Medical, Laguna Hills, CA** **Electrosurgical Design Engineering Consultant**

Designed Micro-surgical instruments and electrosurgical electrodes for minimally invasive gynecological surgical applications. Taught electrosurgical theory to R&D staff, acquired test equipment, and developed electrosurgical test methods and protocols.

1990 1995 **Birtcher Medical Systems – Irvine, CA** **Vice President Research & Development**
Executive Vice President, Operations

Specified and designed Conventional and Argon Beam Coagulation generators and disposable products. Responsible for Intellectual Property development, maintenance, and defense. Multi-functional responsibility in R&D, Regulatory Affairs, Quality Control, Manufacturing/Operations.

1983 1990 **Alcon Surgical – Irvine, Ca** **Manager, Electronics & Software Development, Director of Surgical Product Development**

Designed and developed a low power electrocautery module for ophthalmic surgical applications as part of the Series Ten Thousand Ocutome System.

1981 **Maxwell, Corporation – San Diego, CA** **Plasma Beam Generator control system design for Tokamak Fusion Reactor**

Designed circuitry and algorithms for the Neutral Beam Particle Injector control system for plasma heating in a Tokamak fusion reactor under development by General Atomic Corporation for the US Department of Energy.